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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,131	10/11/2005	Maria-Jesus Blanco-Pillado	X-14441	7160

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ELI LILLY & COMPANY
PATENT DIVISION
P.O. BOX 6288
INDIANAPOLIS, IN 46206-6288

EXAMINER	
CHANG, CELIA C	
ART UNIT	PAPER NUMBER
1625	

NOTIFICATION DATE	DELIVERY MODE
01/22/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary	Application No.	Applicant(s)	
	10/552,131	BLANCO-PILLADO ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,9,14,15 and 29-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1, 29* is/are allowed.

6)☒ Claim(s) *9,14,15 and 30-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. In an appeal conference held on Jan. 8, 2009, it was decided that the finality of the instant application is withdrawn. The brief filed by applicants dated Oct. 7, 2008 is considered a response to the now non-final rejection of Feb. 12, 2008. The argument dated Oct. 7, 2008 is entered and considered carefully.

Claims 1, 9, 14-15, 29-32 are pending.

2. The rejection of claims 1, 9, 14-15 and 29-32 under 35 USC 112 first paragraph for containing new matter is dropped.

In the Oct. 7, 2008 applicants stated that the instant claims wherein R5 is hydrogen and R6 is also hydrogen is the default condition of the proviso disclosed on page 4 of the specification as "R^6 is hydrogen or C_1-C_3 alkyl optionally substituted with one to three fluoro substituents, provided that R^6 may be C_1-C_3 alkyl only when R^5 is other than hydrogen;" . Thus the description of the default when R5 is hydrogen then R6 can only be hydrogen finds support within the four corner of the specification since there is only one default condition.

2. The rejection of claims 29-32 under 35 USC 112 first paragraph for lacking enablement is dropped in view of the newly available information that the vascular dysfunction is one of the cause of migraine (see Parsons et al. or Wikipedia) and on pages167-169 of the specification the specific efficacy of the claimed compounds for treating migraine is supported by the assay of rabbit saphenous vein contraction.

3. The rejection of claims 14-15 and 31-32 under 35 USC 112 first paragraph for lacking description of preventing migraine is dropped. A new ground of rejection is hereby applied.

Claims 14-15, 31-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating migraine, does not reasonably provide enablement for preventing migraine. The specification does not enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Three documents, one from national headache foundation, one from the Mayo Clinic and one from Widipedia are hereby attached for applicants' convenience. In all three documents, it was clearly delineated that for migraine prevention the method is a combination of education, changes in lifestyle such as avoid triggers, exercise etc. and sometimes medication such as reducing estrogen or estrogen replacement etc. Long term use of medication is especially not recommended, and if medication is used, it should cut the frequency by half. In other words, to claim that a drug has the utility or efficacy in "prevention" the parameters of risk and measurement of risk reduction must be evidenced.

It was explained in previous office actions that once a patient is diagnosed with migraine, any maintenance dose is *treating* a *patient* since treatment in avoiding symptom is still treatment. None of the claimed compound has been evidenced to be able to either reduce the risk of migraine candidate, abolish development in genetic predisposed individual or even just meeting the standard of cutting the frequency by half. The specification provided no guidelines as to who is the candidate, how and what dose can be administer, what would be "prevented" i.e. on set of pain, aura or duration of pain etc. as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims according to ordinary standard of the field.

4. The argument with respect to rejection of claims 9 and 30 under 35 USC **first** paragraph is moot because the rejection is under 2nd paragraph for ambiguity.

Applicants should decide whether the preamble "pharmaceutical" composition is limiting or not limiting. Because the term "pharmaceutical composition" according to one having ordinary skill in the pharmaceutical art, must be either ineffective or toxic, because it is by definition a "pharmaceutic". If applicants' intention is a "composition of matter" for which one compound and at least one carrier without quantitative requirement is needed, then, applicants should particularly claiming the subject matter as intended (see 2nd paragraph particularity). It is ambiguous to have a preamble but insisted that the preamble should not be given any meaning and if one does give meaning consistent with the preamble, it is unreasonable limiting. If no

limitation is required by a preamble, then, no preamble should be incorporated to make the scope inconsistent with what applicants are intended for.

5. Claims 1 and 29 are allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Jan. 14, 2009

/Celia Chang/
Primary Examiner
Art Unit 1625